

REMARKS

The Examiner has rejected Claims 1-32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,630,426 to Eggers et al. ("Eggers I") in view of U.S. Patent Application Pub. No. 2003/0100932 to Ciaff ("Ciaff"), U.S. Patent No. 6,287,304 to Eggers et al. ("Eggers II"), and U.S. Patent No. 6,685,729 to Gonzalez ("Gonzalez"). Claims 1-3 are currently pending. The following remarks are considered by applicant to overcome each of the Examiner's outstanding rejections to current Claims 1-3. An early Notice of Allowance is therefore requested.

I. THE CURRENT OFFICE ACTION IS DEFICIENT AND MUST BE REISSUED

Applicants note that Examiner has failed to address key arguments from Applicant's Amendment/Response filed on November 19, 2009. In particular, Applicants previously raised the point that there is no motivation to combine the teachings of Gonzalez with those of the other cited references (i.e., Ciaff).

More specifically, Applicants previously pointed out that the brain (i.e., related to the teachings of Gonzalez) is very different from muscle groups or nerve tissue (i.e., the teachings of the other cited references Ciaff and Raymond). One of skill in the art knows that treatments that work for muscle tissue or nerve tissue do **not** necessarily work for brain tissue. As such, there is **no reasonable expectation of success** that methods of treating muscle tissue or nerve tissue can also be used to treat brain tissue. Thus, according to MPEP § 2143.02, there is **no motivation** to combine the references in the way Examiner suggests.

Examiner has failed to address this previously articulated argument. As such, the current Office Action is **deficient**. Therefore, Applicants respectfully assert that Examiner **must** withdraw the current Office Action and issue either (1) a Notice of Allowance, or (2) a **new non-final** Office Action addressing all of Applicant's previous arguments, as well as the arguments of the current Response.

II. SUMMARY OF RELEVANT LAW

The determination of obviousness rests on whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In determining obviousness, four factors should be weighed: (1) the scope and content of the prior art, (2) the differences between the art and the claims at issue, (3) the level of ordinary skill in the art, and (4) whatever objective evidence may be present. Obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor. The Examiner carries the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness and must show that the references relied on teach or suggest all of the limitations of the claims.

III. REJECTION OF CLAIMS 1-3 UNDER 35 U.S.C. § 103(A) BASED ON EGGERS I IN VIEW OF CIAFF, EGGERS II, AND GONZALEZ

On page 2 of the current Office Action, the Examiner rejects Claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over Eggers I in view of Ciaff, Eggers II, and Gonzalez. These rejections are respectfully traversed and believed overcome in view of the following discussion.

A. The Cited Reference FAIL to Teach or Suggest Removing Any Pathologically Changed Tissue

Claim 1 states, in part:

“treating the area of body tissue, wherein the treatment comprises the probe selecting **and removing** any pathologically changed tissue parts...” (emphasis added).

Accordingly, as stated above, Claim 1 requires that the treatment includes removing any pathologically changed tissue parts.

Eggers I, Ciaff, and Gonzalez all fail to disclose the above language of Claim 1, and Examiner does not assert otherwise. Rather, Examiner asserts that column 4, line 26 to column 6, line 24 of Eggers II discloses this language of Claim 1. However, this section of Eggers II relates to **cauterization** of a targeted tissue volume to **evoke a zone of**

necrosis, and does **not** relate in any way to an actual **removal** of any tissue whatsoever. In fact, column 5, lines 40-49 of Eggers II explicitly states:

“Upon completion of the **cauterization** of the **targeted tissue volume** to **evoke** a zone of **necrosis**, the instrument again is actuated from its base region to **withdraw** the **electrode primary components** into their nested orientation within the instrument. This may optionally be carried out by electrosurgically operating the **electrodes** in a cutting mode during the procedure of **their retraction** to a nested orientation. Upon retrieval of the electrode assemblies to their non-obtrusive nesting orientation, the instrument may be removed for a next procedure.” (emphasis added).

Accordingly, Eggers II relates to operating electrodes in a mode so as to **cauterize** a targeted tissue volume, thereby evoking **necrosis**, and **not** to any **removal** of tissue. See also Eggers II, Col 6, Lns. 8-9 (relating to rapid formation of zones of necrosis). While Eggers may disclose **retraction** of the **electrodes**, this is **not** a **removal** of any **tissue**. In fact, this disclosure of **Eggers II** is **not** significantly different from the tissue **cauterization** treatment of **Eggers I** (see Eggers I, Col. 6, Lns. 53-58), which Examiner pointed does **not** assert discloses any **removal** of tissue. This is likely because cauterization does **not** relate to tissue **removal**, but **rather** relates to **burning** cells (in this case by electric current). This results in cell **death** (i.e., necrosis), and **not** to cell **removal**. Eggers II, Col. 4, Lns. 39-42. Thus, Eggers II does **not** disclose or render obvious the selection **and removal** of pathologically altered tissue parts, as required by Claim 1.

Moreover, neither Ciaff nor Gonzalez cure this deficiency of Eggers I and Eggers II.

In particular, paragraph [0013] of Ciaff explicitly states:

“[0013] Typically, a patient might describe their symptoms in terms of a muscle feeling “a bit weak”. Traditionally, the clinician assesses muscular weakness and lack of strength using a grading system of 1 to 5 for strength and movement--or in a more advanced method by isokinetic evaluation. Using conventional diagnostic methods, it has been difficult for Clinicians to **evaluate** whether the problem was lack of strength--or some other finite neuro-muscular problem, eg, whether there was a pain inhibition pattern or a malfunctioning muscle. **The apparatus of the invention** provides the clinician with a more detailed **analysis** of the recruitment behaviour of a muscle group enabling him to distinguish various forms of neuro-muscular anomalie.” (emphasis added).

Accordingly, Ciaff relates to **analysis/evaluation** of muscle groups, and **not** to **removal** of tissue. Thus, neither paragraph [0013] nor in any other portion of Ciaff discloses or renders obvious the selection **and removal** of pathologically altered tissue parts, as required by Claim 1.

Similarly, Gonzalez relates to **stimulation** of the area of dysfunction, spine and head, and **not** to **removal** of tissue. Gonzalez, Col 11, Lns. 40-49. While the Examiner points to Gonzalez as disclosing a solution for testing brain tissue, wherein the tissue is stimulated, defects are corrected, and stimulation is continued until normal function has been established, Gonzalez fails to disclose any **removal** of brain tissue.

More specifically, the solution described in Gonzalez concerns a method for testing, identifying and treating areas of aberrant sensory or motor ability and includes implementation of sensory or motor function tests.

Dysfunctional areas are identified and subsequently stimulated by therapeutic means until no further dysfunction, particularly neurological dysfunction, can be determined by new function tests.

In Gonzalez, the probe is positioned in the organ to be treated, or is moved toward that area, after a diagnostic examination has been carried out (sensory or motor function tests). The tissue selection is carried out by evaluating the stimulus response given by the tissue in question as the result of stimulus by different electric/electronic signals.

In contrast to the solution described in Gonzalez, in which it is attempted to regenerate the diseased tissue by stimulating the nerves leading to the diseased tissue region (see Figure 2A, reference number 32, and column 5, lines 60-65), the diseased tissue is **removed** in the solution of Claim 1. Therapy is merely an additional option in the solution of Claim 1.

While the solution of Gonzalez does relate to application in the brain, Gonzalez is concerned with testing and reanimating brain tissue. Gonzalez does **not** describe a **surgical** procedure to **remove** the pathologically altered tissue, nor is this rendered obvious.

Thus, **none** of the references to which Examiner cites teach or suggest a treatment that comprises the probe selecting **and removing** any pathologically changed tissue parts, as required by Claim 1.

B. The Cited Reference FAIL to Teach or Suggest Repositioning the Probe When a Pathologically Changed Tissue Part is Detected

Claim 1 also states, in part:

“wherein, if the tissue stimulation **does not identify a pathologically changed tissue part**, the probe is **repositioned** and a new area of body tissue is stimulated.” (emphasis added).

Examiner asserts that Eggers I discloses the above language of Claim 1.

The above language of Claim 1 specifically states that the probe is repositioned **when the tissue stimulation does not identify a pathologically changed tissue part**. Examiner asserts that column 10, line 64 to column 11, line 11 of Eggers I discloses this claim limitation.

However, this portion of Eggers I relates to “the ability to iterate between treatment and measuring modes of operation.” Eggers I, Col 10, Lns. 64-66. In other words, this portion of Eggers I teaches performing **treatment** at a first location, **then moving** the probe to a new position and repeating the treatment. Eggers I, Col. 11, Lns. 3-5. Eggers I then goes on to say that the treated region might be measures again, **followed by resumed treatment**, thus **alternating** between **diagnostic** and **treatment**. Eggers I, Col. 11, Lns. 6-11. As such, Eggers only teaches moving the probe **after treatment**, and **not after a failure** to identify a pathologically changed tissue part, as required by Claim 1.

Thus, the combination of the cited references fails to teach or suggest the above language of Claim 1.

C. The Cited Reference FAIL to Teach or Suggest Identifying Any Pathologically Changed Tissue Parts By Identifying a Response Which Is a Change To the Body's Functioning Distinct From the Properties of the Body Tissue Being Stimulated

In addition, Claim 1 states, in part:

“**identifying** any pathologically changed tissue parts in the area of body tissue **by identifying** those tissue parts for which the person being treated provides no stimulus response or an unexpected stimulus response, **wherein the response identified is a change to the body's functioning distinct from**

**the properties of the body tissue being
stimulated....” (emphasis added**

Examiner asserts that column 6, lines 46-52 of Eggers I discloses the above language of Claim 1. However, this portion of Eggers I explicitly states:

“Moreover, by **comparing** the parameter value indicated on sensory display 45 to a table of predetermined values, it is possible for the operator to **characterize the tissue being measured**. This is accomplished, for example, by **measuring the difference in electrical impedance between tissue known to be normal and tissue suspected of being malignant.**”

Eggers, Col. 6, Lns. 46-52 (emphasis added).

In other words, the impedance of a selected portion of tissue is measured, and then the **difference** between that **measured impedance** value and the **known impedance** value for normal tissue is used to **determine** whether the tissue is malignant. As such, the **response** of Eggers I has **nothing whatsoever** to do with any part of the **body’s functioning**. Thus, the teachings of Eggers I are **very different** from the method of Claim 1, in which the **response** identified is a **change** to the **body’s functioning** distinct from the properties of the body tissue being stimulated.

In addition, as discussed in Applicants’ Amendment and Response previously filed on May 7, 2008, Claim 1 requires identifying a stimulus response “distinct from the properties of the body tissue being stimulated” A stimulus response could be hearing loss or tremors or any number of responses, but the stimulus response must be “distinct from the properties of the body tissue being stimulated” The electrical impedance of an object, on the other hand, is by definition the object’s preexisting resistance to the flow of electrical current. **Thus, electrical impedance is a property of body tissue.** Accordingly, Eggers I’s disclosure of measuring the impedance of body tissue does **not** disclose identifying a stimulus response “distinct from the properties of the body tissue being stimulated”

Also as discussed in Applicants’ Amendment and Response previously filed on May 7, 2008, Claim 1 is further distinguished from Eggers I by specifying that the stimulus response must be “**a change to the body’s functioning** distinct from the properties of the body tissue being stimulated” A tissue’s impedance—it’s preexisting

resistance to the flow of electrical current—is **not** a change to the **body's functioning**. Rather, it is a **constant property** of the body tissue being stimulated.

Thus, the combination of the cited references fails to teach or suggest the above language of Claim 1.

D. There is NO Motivation to Combine the Teachings of Gonzalez with Those of Eggers I, Ciaff, or Eggers II

Claim 1 states, in part:

“placing a probe in an area of **body tissue of a brain** of
a body of a person being treated;

Thus, the entire method of Claim 1 relates to treating body tissue of **a brain**. Examiner admits that Eggers I, Ciaff, and Eggers II fail to disclose treatment of **brain tissue**. Rather, Examiner cites to Gonzalez as disclosing testing brain tissue in an iterative test where tissue is stimulated, corrected of any defects, and re-stimulated/tested until functioning normally. Examiner then asserts that it would have been obvious to modify the methods of Eggers I, Ciaff, and Eggers II in order to test brain tissue. This, however, misinterprets the teachings of the references.

In particular, the **brain** is very different from muscle groups or nerve tissue. One of skill in the art knows that treatments that work for muscle tissue or nerve tissue do not necessarily work for brain tissue. As such, there is no reasonable expectation of success that methods of treating muscle tissue or nerve tissue can also be used to treat brain tissue. Thus, according to MPEP § 2143.02, there is **no** motivation to combine the references in the way Examiner suggests.

E. Conclusion

Accordingly, for all the reasons discussed above, Applicants respectfully assert that Examiner has failed to establish a prima facie case of obviousness of independent Claim 1, and corresponding Claims 2 and 3 because they are each ultimately dependant from independent Claim 1. Therefore, Applicant respectfully requests that Examiner withdraw the rejection of Claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,630,426 to Eggers et al. in view of U.S. Patent

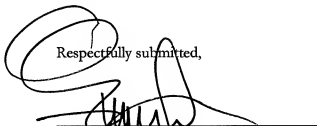
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Application Pub. No. 2003/0100932 to Ciaff, U.S. Patent No. 6,287,304 to Eggers et al., and
U.S. Patent No. 6,685,729 to Gonzalez.

Based upon the above remarks, Applicant respectfully requests reconsideration of this application and its early allowance. Should the Examiner feel that a telephone conference with Applicant's attorney would expedite the prosecution of this application, the Examiner is urged to contact him at the number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Eugene LeDonne', is written over a horizontal line. To the left of the signature is a large, loopy circular mark.

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